Testing for Chlamydial Infection

Chlamydia trachomatis infection is the most prevalent bacterial sexually transmitted disease in the United States, causing more than 4 million infections annually at a cost of about $2 billion. Although men and infants are also affected, women are at greatest risk for serious complications, including adverse reproductive consequences such as ectopic pregnancy and infertility. To minimize the risk for these tragic outcomes and prevent further transmission, timely diagnosis and appropriate treatment are essential.

Several diagnostic tests for chlamydial infections are now available, but they vary considerably in their cost, reliability, and availability. The two methods currently used to routinely screen for and diagnose chlamydial infection are culture and antigen detection. Culture is considered to be the definitive method of diagnosing a chlamydial infection. This method, however, is expensive—at the time of writing, as much as $30 per test—because isolating *C trachomatis* requires cell culture techniques similar to those used to detect viruses. Moreover, culture requires two to four days before results are available. For these reasons, culture is more widely used by investigators than clinicians.

Two antigen-detection approaches are currently available: direct immunofluorescent staining of smears using monoclonal antibodies, and the detection of chlamydial antigen from swabs measured by enzyme-linked immunosorbent assay (ELISA). Compared with culture, antigen detection is less expensive (cost usually less than a third as much), technically easier, and may provide results within a couple of hours. The two antigen-detection tests most comprehensively evaluated are Microtrak (direct smear test) and Chlamydiazyme (ELISA). Overall, they appear to be of comparable sensitivity and specificity compared with culture, although some data suggest that the direct smear test may have a slightly higher sensitivity in urethral infections in men and specificity in cervical infections. Studies of the direct smear test show the sensitivity ranging from 60% to 100% and specificity ranging from 72% to 99%, depending on the population studied. For the enzyme immunoassay, the sensitivity ranges from 50% to 98% and specificity from 93% to 100%. Both tests appear to be associated with better results in women with cervical infection than in men with urethral infection and in symptomatic patients than in asymptomatic patients, where fewer inclusion-forming units are found. The direct smear test has also been used to detect eye and rectal infections. One distinction between the two antigen-detection tests is how they are processed: The direct smear test is labor-intensive, requiring a high-quality fluorescent microscope and an experienced microscopist, while the ELISA is less labor-intensive and more automated but requires more specialized laboratory equipment (a spectrophotometer).

Serology and cytology are the other two methods of detecting *C trachomatis*, but both are infrequently used in clinical settings. In addition to being a research tool, serology has been used to evaluate infertility in women. Cytologic methods are not routinely used primarily owing to their low sensitivity. Women with Papanicolaou smears suggestive of chlamydial infection should, in particular, receive a confirmatory test—that is, culture or antigen-detection test.

In collecting a specimen to diagnose chlamydial infection, special care should be taken to ensure that the cervical os is cleaned of mucus and debris with a swab before the specimen is obtained and that epithelial cells are collected on specimens obtained by scraping the urethra, cervix, or rectum. Because chlamydiae are obligate intracellular pathogens, specimens obtained from purulent discharges, secretions, or urine are inappropriate. In addition, specimens should be processed as instructed by laboratory protocol. This will, at a minimum, entail immediately placing the specimen in transport medium and providing timely refrigeration.

When chlamydial infection is diagnosed, patients should be treated immediately with an effective regimen. All sex partners should be examined for sexually transmitted disease and also treated promptly for *C trachomatis* with an effective regimen.

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